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K003175

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Pty Ltd. summary for the Compumedics Siesta System.

SUBMITTER'S NAME:	Compumedics Telemed Pty Ltd
ADDRESS:	1 Marine Parade, Abbotsford, Victoria, 3067 Australia
CONTACT PERSON:	Constance Bundy, C.G. Bundy Associates, Inc.
TELEPHONE NUMBER:	612-574-1976
FAX NUMBER:	612-571-2437
DATE OF SUBMISSION:	October 6, 2000

1. Identification of device

Proprietary Name: Compumedics Siesta System
Common Name: Electroencephalograph
Classification Status: Class II per regulations 882.1400
Product Codes: GWQ

2. Equivalent devices

Compumedics believes the Compumedics Siesta System is substantially equivalent to the Compumedics Sleep Monitoring System, *510(k) No:* K955841 and Compumedics E-Series EEG System, *510(k) No:* K000068.

3. Description of the Device

The Compumedics Siesta System is a multi-functional ambulatory recording device. The system is used for the recording, monitoring, storage and transfer of up to 32 biophysical parameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, and body movements. In addition it has an Oximeter interface for heart rate and oxygen saturation as well as supporting up to 16 serial ports for the connection of external devices such as pH meters.

Electrodes and sensors from the patient are connected to adaptors, which are in turn connected to the Siesta Recording Unit.

Patient Studies recorded using the Siesta and ProFusion PSG Software allow the user to view, print, summarize, analyze and create Patient Study reports.

The Siesta Recording Unit has a built in Compact Flash Disk interface for storage and convenient transfer to review workstations. There is no proprietary hardware required to transfer the study data.

A built in wireless Radio LAN module allows the Siesta Recording Unit to remotely monitor study parameters.

Battery power can be used to power the unit for up to 24 hours of continuous operation, depending upon use of Radio LAN and configuration of study. The unit supports both rechargeable and non-rechargeable batteries as well as an external main powered combination power supply/battery charger.

4. Intended use

The Siesta System is intended for use in the recording, displaying, monitoring, printing and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders.

The Siesta System unit is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Siesta System is only to be used under the direction and supervision of a physician, EEG technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

5. Technological characteristics, comparison to predicate device.

Like the predicate devices, the Compumedics Siesta System is intended to detect physiological signals from various points on the patient's body, individually or as a signal measured between selected electrodes, and to record those signals in accordance with preset parameters (in a montage) for analysis by a clinician.

Comparison Table:

Characteristic	*Compumedics Sleep Monitoring System (P-Series)*	*Compumedics Siesta System*	*Compumedics E-Series System*
Intended Use	For use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders	Same	Same
Configuration	Waist belt or desktop	Waist belt or desktop	Desktop
Number of patients can monitor simultaneously	1 per Unit	1 per Unit	1 per Unit
Portable Design	Yes	Yes	No
Data Collection	Yes	Yes	Yes
Data Analysis	Optional	Optional	Optional
Report Generation	Optional	Optional	Optional
Capable of Data Transfer for Analysis and Report Generation	Yes	Yes	Yes
Channels	16 or 24	32	44 or 64
Data Input Types	ECG, Neurological, Respiratory	ECG, Neurological, Respiratory	ECG, Neurological, Respiratory
Remote Capability to Monitor Lead Quality	Yes	Yes	Yes
Remote Capability to Monitor Recording Parameters	Yes	Yes	Yes
Electrode Imped. Check	Yes	Yes	Yes
Calibration Check	Yes	Yes	Yes
Selectable Montage Configuration	Yes	Yes	Yes
Annotations on study	Yes	Yes	Yes
Raw data storage	Flashcard	Hard disk, Flashcard	Hard disk
Study Modes	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay
Optional Equipment	Time Sync Video/Digital Video/Printer	Digital Video/Printer	Time Sync Video/Digital Video/Printer
Radio LAN Capabilities	No	Yes	No

6. Discussion of performance testing.

An extensive collection of tests has been conducted and successfully completed, including safety, performance and comparative tests.

7. Conclusion

It is the conclusion of Compumedics that the Siesta System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Compumedics Telemed Pty, Ltd.
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K003175
Trade Name: Compumedics Siesta System
Regulatory Class: II
Product Code: GWQ
Dated: October 6, 2000
Received: October 10, 2000

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for ~~the indications for~~ use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, ~~or to devices that~~ have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the ~~general controls~~ provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K003175

Device Name: Siesta System

Indications for Use:

The Siesta System is intended for use in the recording, displaying, monitoring, printing and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders.

The Siesta System is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Siesta System is only to be used under the direction and supervision of a physician, EEG technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Re... ...vices
510(k) Number K003175

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)